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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,432	07/17/2003	Gary A. Strobel	34373/0007	4064

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,432	Applicant(s) STROBEL ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60,61 and 64-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60,61 and 64-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of “mehtyl” in claim 65.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

The preliminary amendment filed 2/21/06 is acknowledged. Claims 60-61 and 64-71 are being considered on the merits.

In the specification at least at section [00035] a hyperlink is provided. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60-61 and 64-71 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 64-71 are vague and indefinite in the recitation “*Muscodor*-derived composition”, since it is unclear how the composition is “derived”. Amendment to -- obtained from *Muscodor* - would be remedial.

Claims 64-71 are vague and indefinite in the recitation of “exposing the organism or a habitat of the organism to a pesticidally effective amount...”. To begin with “exposing” does not set forth whether contact with the target is or is not achieved. Moreover, the amount intended by “pesticidally effective amount” is not delineated with sufficient particularity, especially since a maximum but not a minimum is defined for some of the volatile compounds and the pest is not

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identified with any particularity. An amount required for a microbe might be insufficient for an insect, such as a grasshopper having a field as its habitat, for example.

Claim 61 is vague, indefinite and confusing in the recitation “toxic mold”, since there is no clear indication as to the target of the toxicity. In addition, the claims is confusing in that the nature of “building materials” and of “spaces between building materials” cannot be readily assessed. The broadest reasonable definition of definition of “building materials” includes paper, cardboard, metal, molding clay, wood, plastic, bricks and concrete, etc. In addition the scope of the distance between these materials is not claim designated with sufficient particularity.

Claims 60-61 and 64-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 recites, “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by ‘whatever characteristics sufficiently distinguish it’. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.”

The claims are broadly drawn to the use of certain organic volatile compounds to inhibit the growth of any microbe, any insect and any nematode. For example, claims 64 and 65 read on providing a trace of 2-methyl-1-butanol or isobutyric acid. In contrast, the specification only provides guidance for the treatment of certain fungi, a few specific insects, a few specific bacteria and one nematode *in vitro*, using specific mixtures of volatile compounds. No guidance is presented regarding the structure/function relationship between the use of one or a few volatile compounds in combination in undisclosed amounts and their application *in vivo*, for the inhibition of growth of microbes having as their habitat an animal and/or human and cause diseases. The disclosed methods are not representative of the inhibition of any microbe, insect

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and nematode with one or more of "*Muscodor*- derived" volatile compounds as claimed in any environment whatsoever, including the human body, because no known correlation is shown between the use of one or two volatiles in trace amounts and the claimed effects. There is no clear indication that one or more of the recited compounds regardless of their source and in trace amounts would have the required inhibitory effects. Thus it is not apparent that the disclosure provided is reasonably predictive of the activity of the recited volatile compounds as claimed.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

Claims 60-61 and 64-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of certain fungi with a mixture of volatile compounds produced by *Muscodor*, does not reasonably provide enablement for the inhibition of any microbe, insect or nematode using certain volatiles singly or in combination in any amount..

The inhibition of microbes, insects and nematodes with volatile compounds is unpredictable particularly when using trace amounts. The specification as-filed does not provide sufficient guidelines or teachings for the inhibition of any and all microbes, including intracellular bacteria such as *Mycobacterium* or *Chlamydia* or pathogenic bacteria, such as *Listeria*, *Legionella*, *Borrelia burgdorferi* or any and all viruses, since there is no guidance regarding the dosage and mode of administration of the volatile compounds *in vivo*. It is noted that some of which volatiles listed are toxic. The teachings provided in the as-filed specification would not have enabled one skilled in the art to "use" the *Muscodor*-derived volatile compounds to inhibit any microbe, insect or nematode in the claim designated methods. The guidance provided in the specification is not adequate to lead persons of skill in the art toward success in inhibiting all the organisms recited in the process encompassed by the claims in a predictable manner, because the effects of single compounds are not set forth with any particularity and the amounts required for effectiveness are not specified with sufficient particularity. It is apparent that applicant is offering an "invitation to experiment" to those skilled in the art to perform various techniques and to determine for themselves whether they have inhibited the growth of a microbe, insect or nematode. See *Genentech, Inc. v Novo Nordisk A/S*, 42 USPQ2d, 1001, 1005 (Fed. Cir. 1997) ("Tossing out the mere germ of an idea does not constitute an enabling disclosure"). Also, *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974) ("It is not enough that a

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person skilled in the art, by carrying out investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves. In re Gardner et al., 166 USPQ 138 (1970)").

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to identify the volatile compound(s) necessary to inhibit the growth of any and all microbes, any and all insects at any stage and any and all nematodes; limited amount of guidance and limited number of working examples in the specification directed to the treatment of a large variety of members of the organisms recited with combinations of compounds; the unpredictable nature of an invention directed to the use of single or specific combinations of volatile compounds in any amount to inhibit the growth of any and all microbes, any and all insects at any stage and any and all nematodes; the unpredictability in the art and breadth of the claims directed to the use of certain volatiles singly or in certain combinations to inhibit the growth of any and all microbes, any and all insects at any stage and any and all nematodes. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60, 64 and 70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nandi *et al.*.

The claims are directed to a process of inhibiting any microbe with ethyl butyrate.

Nandi *et al.* disclose a process of inhibiting fungi by exposing to ethyl butyrate. See, e.g., Table 3.

The limitation of "Muscodor-derived" is not deemed to distinguish a chemical compound such as ethyl butyrate.

Claims 64 and 70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rathore *et al.*.

The claims are directed to a process of inhibiting any microbe with ethyl butyrate.

Rathore *et al.* disclose a process of inhibiting fungi by exposing to ethyl butyrate or ethyl propionate. See, e.g., Table 1.

The limitation of "Muscodor-derived" is not deemed to distinguish chemical compounds such as ethyl butyrate or ethyl propionate..

Claims 64 and 70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Robinson *et al.*

The claims are directed to a process of inhibiting any microbe with ethyl butyrate.

Robinson *et al.* disclose a process of inhibiting fungi by exposing to isobutanol. See, e.g., Table 1.

The limitation of "Muscodor-derived" is not deemed to distinguish chemical compounds such as ethyl butyrate or ethyl propionate..

Claims 60, 64 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartelt *et al.*

The claims are directed to a process of inhibiting growth of any insect with 2-methyl-1-butanol and/or 3-methyl-1-butanol .

Bartelt *et al.* disclose a process of exposing insects to 2-methyl-1-butanol and/or 3-methyl-1-butanol. Growth is inherently inhibited at least to some extent. See, e.g., page 2449, col. 2, page 2450, col. 1, Figure 2.

The limitation of "Muscodor-derived" is not deemed to distinguish chemical compounds such as 2-methyl-1-butanol and/or 3-methyl-1-butanol.

Claims 64 and 65 are rejected under 35 U.S.C. 102(a) as being anticipated by Landolt *et al.*

The claims are directed to a process of inhibiting growth of any insect with 2-methyl-1-butanol and/or isobutanol .

Landolt *et al.* disclose a process of exposing insects to 2-methyl-1-butanol and/or isobutanol. Growth is inherently inhibited at least to some extent. See, e.g., Table 2, page 1616.

The limitation of "Muscodor-derived" is not deemed to distinguish chemical compounds such as 2-methyl-1-butanol and/or isobutanol.

Claims 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Nout *et al.*

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The claims are directed to a process of inhibiting growth of any insect with certain compounds and mixtures thereof.

Nout *et al.* disclose a process of exposing insects to 2-methyl-1-butanol, 3-methyl-1-butanol, ethyl propionate and 2-phenylethanol. Growth is inherently inhibited at least to some extent. See, e.g., Table 2 and page 1229, paragraph 1.

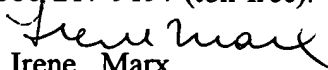
The limitation of "Muscodor-derived" is not deemed to distinguish chemical compounds such as 2-methyl-1-butanol, 3-methyl-1-butanol, ethyl propionate and 2-phenylethanol.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
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